

Applicant : Yi-Jyun Lin et al.
Serial No. : 09/978,486
Filed : October 15, 2001
Page : 6

Attorney's Docket No.: 06618-343002 /
CIT 2857D

REMARKS

These remarks are in response to the Office Action dated June 26, 2002. Claims 18 and 20 are allowable. Claims 1, 4, 9, 17, 19, 21 and 22 have been amended. Support for the amendments can be found throughout the specification. For example, support for "embryonic lethality in Drosophila," as recited in claims 1, 4 and 21, can be found at page 78, lines 20-22 and Figures 1 and 2. Support for "GPCR," as recited in claims 1, 4 and 21, can be found at page 6, lines 15-23 and Figure 4. Support for "modulates the effect of heat stress in Drosophila," as recited in claims 1, 4 and 21, can be found at page 78, lines 22-24 and Figures 2A-2C, as well as page 78, lines 24-27 and Figures 2A-2C. No new matter has been added.

Applicants representative wish to thank the Examiner for her helpful comments and suggestions during the telephone interview of June 24, 2002. Attached is a marked-up version of the changes being made by the current amendment. Claims 1-4 and 6-22 are pending and at issue. Applicants respectfully request reconsideration of the present application.

OBJECTIONS

The Office Action states at part 3 that there are sequences in Figure 4 that lack sequence identifiers. Applicants note that the appropriate paragraph in the specification has been amended to include the requested sequence identifier information for Figure 4.

I. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Written Description

Claim 21 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter for the recitation of "at least 15 contiguous amino acids." While Applicants traverse this rejection, Applicants note that the recitation of "at least 15 contiguous amino acids" has been deleted from the claims.

Claims 1-3, 4-8, 15, 16 and 21 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection as applied to the amended claims.

Specifically, the Office Action alleges that there is "no measurable function associated with SEQ ID NO:2." Applicants note that claims 1, 4 and 21 have been amended to recite functional characteristics of the polypeptide set forth in SEQ ID NO:2, such as 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in *Drosophila*, and 3) the polypeptide modulates the effect of heat stress in *Drosophila*. Applicants believe that these amendments render the rejection moot with regard to independent claims 1, 4 and 21 and the claims which depend therefrom. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Claims 9-17 and 22 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. While Applicants traverse this rejection, Applicants have amended claims 9 and 22 to recite "consisting of an antigenic fragment." Applicants believe that this amendment renders the rejection moot.

II. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Enablement

Claims 1-3, 4-8, 15, 16 and 21 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one of skill in the art to make or use the invention. Applicants respectfully traverse this rejection.

Specifically, the Office Action alleges that there is "no particular activity associated with SEQ ID NO:2." Applicants note that claims 1, 4 and 21 have been amended to recite activities of the polypeptide set forth in SEQ ID NO:2, such as 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in *Drosophila*, and 3) the polypeptide modulates the effect of heat stress in *Drosophila*. Applicants believe that these amendments render the rejection moot with regard to independent claims 1, 4 and 21 and the claims which depend therefrom. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

Claims 9-17 and 22 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. While Applicants traverse this rejection, Applicants have amended

claims 9 and 22 to recite "consisting of an antigenic fragment."
Applicants believe that this amendment renders the rejection
moot.

Claims 1-4, 6-8, 15, 16 and 21 stand rejected under 35
U.S.C. §112, second paragraph, as allegedly indefinite for the
recitation of "stringent conditions" or "highly stringent
conditions" and of "functional activity." While Applicants
traverse this rejection, Applicants have amended claims 1, 4 and
21 to eliminate the aforementioned terms. Applicants believe
that this amendment renders the rejection moot.

Claims 9-17 and 22 stand rejected under 35 U.S.C. §112,
second paragraph, as allegedly indefinite because it is unclear
which polypeptides are referred to in the preamble. While
Applicants traverse this rejection, Applicants have amended
claims 9 and 22 to recite "consisting of an antigenic fragment."
Applicants believe that this amendment renders the rejection
moot.

Claim 17 stands rejected under 35 U.S.C. §112, second
paragraph, as allegedly indefinite in the recitation of the
final polypeptide. While Applicants traverse this rejection,
Applicants have amended claim 17 to recite "wherein the antibody
specifically binds to the polypeptide comprising SEQ ID NO:2,"
as suggested by the Examiner. Applicants believe that this
amendment renders the rejection moot.

Claim 19 stands rejected under 35 U.S.C. §112, second
paragraph, as allegedly indefinite for the recitation of "a

Applicant : Yi-Jyun Lin et al.
Serial No. : 09/978,486
Filed : October 15, 2001
Page : 10

Attorney's Docket No.: 06618-343002 /
CIT 2857D

polypeptide located in a hydrophilic domain." While Applicants traverse this rejection, Applicants have amended claim 19 to recite "An antibody that selectively binds the hydrophilic domain ...". Applicants believe that this amendment renders the rejection moot.

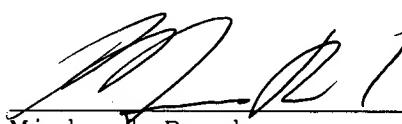
In summary, for the reasons set forth herein, Applicants maintain that claims 1-4 and 6-22 clearly and patentably define the invention. Applicants request that the Examiner reconsider the various grounds set forth in the Office Action and allow the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (858) 678-5070. Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date: _____

9/24/02



Michael Reed
Reg. No. 45,647

Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Version with markings to show changes made

In the specification:

Paragraph beginning at page 6, line 15 has been amended as follows:

FIG. 4 shows the alignment of MTH with several known G-protein coupled receptors. The predicted MTH protein is aligned to partial sequences of the human leukocyte surface antigen CD97 (hCD97, GenBank accession number P48960, SEQ ID NO:3), rat α -latrotoxin receptor (rLR, U72487, SEQ ID NO:4), and mouse EGF-module-containing receptor (mEMR-1, Q61549, SEQ ID NO:5).. Dark shading indicates identity, gray shading similarity. The seven transmembrane domains of MTH are indicated by lines above each row. Consensus amino acids are cited below; similar residues are indicated by dots.

In the claims:

Claims 18 and 20 are allowed.

Claims 2, 3, 6-8 and 10-16 are reiterated.

Claims 1, 4, 9, 17, 19, 21 and 22 have been amended as follows:

1. (Twice Amended) An antibody that selectively binds to a polypeptide selected from the group consisting of:

a) a polypeptide encoded by a nucleic acid molecule which hybridizes in 0.1 x SSC at 68°C to a nucleic acid molecule comprising SEQ ID NO:1, [under highly stringent conditions, wherein the polypeptide retains the functional activity of an mth polypeptide] wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila;

b) a polypeptide comprising an amino acid sequence which is at least 85% homologous to the amino acid sequence of SEQ ID NO:2, wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila [retains the functional activity of an mth polypeptide]; and

c) a polypeptide comprising amino acid residues 1 to 200 of SEQ ID NO:2.

2. (Reiterated) The antibody of claim 1, wherein the antibody is polyclonal.

3. (Reiterated) The antibody of claim 1, wherein the antibody is monoclonal.

4. (Twice Amended) A kit useful for the detection of a polypeptide, the kit comprising a carrier containing one or more containers comprising a first container containing an antibody that selectively binds to a polypeptide selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 0.1 x SSC at 68°C to a nucleic acid molecule comprising SEQ ID NO:1; [under highly stringent conditions, wherein the polypeptide retains the functional activity of an mth polypeptide] wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila;

b) a polypeptide comprising an amino acid sequence which is at least 85% homologous to the amino acid sequence of SEQ ID NO:2, [and] wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila [the polypeptide retains the functional activity of an mth polypeptide]; and

c) a polypeptide comprising amino acid residues 1 to 200 of SEQ ID NO:2.

6. (Reiterated) The kit of claim 4, wherein the antibody is a human antibody.

7. (Reiterated) The kit of claim 6, wherein the antibody is monoclonal.

8. (Reiterated) The kit of claim 6, wherein the antibody is polyclonal.

9. (Amended) An isolated antibody or fragment thereof that selectively binds to [a polypeptide selected from the group consisting of]:

- a) a polypeptide comprising SEQ ID NO:2;
- b) a polypeptide comprising amino acid residues 1 to 200 of SEQ ID NO:2;
- c) a polypeptide [comprising] consisting of an antigenic fragment of SEQ ID NO:2; or
- d) a polypeptide consisting of a fragment of SEQ ID NO:2, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO:2.

10. (Reiterated) The antibody of claim 9, which is a monoclonal antibody.

11. (Reiterated) The antibody of claim 9, which is a polyclonal antibody.

12. (Reiterated) The antibody of claim 9, which is a humanized antibody.

13. (Reiterated) The antibody or fragment thereof of claim 9, which is a human antibody.

14. (Reiterated) The antibody or fragment thereof of claim 9, which is a single chain antibody.

15. (Reiterated) A composition comprising the antibody of claims 1 or 9 and a pharmaceutically acceptable carrier.

16. (Reiterated) A hybridoma cell line that produces a monoclonal antibody according to claim 1 or claim 9.

17. (Amended) An isolated antibody or fragment thereof produced by immunizing an animal with [a polypeptide selected from the group consisting of]:

- a) a polypeptide comprising SEQ ID NO:2;
- b) a polypeptide comprising amino acid residues 1 to 200 of SEQ ID NO:2;
- c) a polypeptide [comprising] consisting of an antigenic fragment of SEQ ID NO:2; or

d) a polypeptide consisting of a fragment of SEQ ID NO:2, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO:2,

wherein the antibody specifically binds to the polypeptide comprising SEQ ID NO:2.

18. (Allowed) An antibody produced by immunizing an animal with a polypeptide having an amino acid sequence as set forth in SEQ ID NO:2, which antibody specifically binds to the polypeptide.

19. (Amended) An antibody that selectively binds [a polypeptide located in] the hydrophilic domain of an mth [protein] polypeptide between hydrophobic domains five and six of SEQ ID NO:2.

20. (Allowed) An antibody that selectively binds to a polypeptide comprising amino acids 407-420 of SEQ ID NO:2.

21. (Amended) A kit comprising an antibody which selectively binds to a polypeptide selected from the group consisting of:

a) a fragment of [a polypeptide comprising] the amino acid sequence of SEQ ID NO:2, wherein 1) the fragment is a GPCR, 2) failure to express the fragment results in embryonic lethality in Drosophila, and 3) the fragment modulates the effect of heat stress in Drosophila [the fragment comprises at least 15 contiguous amino acids of SEQ ID NO:2];

b) a polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 0.1 x SSC at 68°C to a nucleic acid molecule comprising SEQ ID NO:1, [under highly stringent

conditions] wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila; and

c) a polypeptide comprising an amino acid sequence which is at least 85% homologous to the amino acid sequence of SEQ ID NO:2, wherein 1) the polypeptide is a GPCR, 2) failure to express the polypeptide results in embryonic lethality in Drosophila, and 3) the polypeptide modulates the effect of heat stress in Drosophila [the polypeptide retains the functional activity of an mth polypeptide],

and instructions for use.

22. (Amended) A kit comprising an antibody which selectively binds to [a polypeptide selected from the group consisting of]:

a) a polypeptide comprising SEQ ID NO:2;
b) a polypeptide comprising amino acid residues 1 to 200 of SEQ ID NO:2;

c) a polypeptide [comprising] consisting of an antigenic fragment of SEQ ID NO:2; or

d) a polypeptide consisting of a fragment of SEQ ID NO:2, wherein said fragment comprises at least 50 contiguous amino acid residues of SEQ ID NO:2.